

35. (Amended) The method of claim 33-~~or~~ 34, further comprising preparing a formulation including an identified hedgehog fgf-10 antagonist and a pharmaceutically acceptable excipient.

REMARKS

Claims 1-15 and 22-36 constitute the pending claims in the present application. Applicants cancel, without prejudice, claims 3, 6-15, 23, 29-33 and 36. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note with appreciation that the amendments filed June 24, 2002 have been entered. Claims 1-15 and 22-36 are pending and under examination.

2-3. Applicants note with appreciation that the rejection of claims 1, 3, 25 and 26 under 35 U.S.C. 102(a) has been withdrawn. Applicants further note that the rejection of claims 6-15 and 29-32 under 35 U.S.C. 112, first paragraph, has been withdrawn.

4. Claims 1, 2, 3, 4, 5, 25 and 26 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Fujita et al. Applicants traverse this rejection to the extent it is maintained over the amended claims.

The standard for anticipating a claim is clearly outlined in MPEP 2131, and this standard is further supported by the Courts. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1978). "The identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Fujita et al. fail to teach a method for inhibiting proliferation and growth of lung cancer tissue by inhibiting hedgehog expression in the mesenchymal cells which surround the lung cancer tissue, as set forth in the claims. In fact, the in vitro system employed by Fujita et al. would not even have allowed the investigators to assess whether administration of hedgehog

antibodies would result in decreased expression of hedgehog in the surrounding mesenchymal tissue. Additionally, as previously pointed out by Applicants, Fujita et al. fail to teach in vivo methods for inhibiting growth of lung cancer tissue. Accordingly, Fujita et al. fail to satisfy the criteria for anticipating the claimed subject matter. Reconsideration and withdrawal of this rejection is respectfully requested.

5. Claims 22, 23, 27, 28, 34 and 35 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Fujita et al. in light of US 6261786. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

As detailed in the previous Office Action, the above cited combination of references is being applied to the use of small molecule inhibitors of hedgehog signaling. Although, as outlined in detail above, Applicants maintain that Fujita et al. fail to satisfy the criteria for undermining the patentability of the claimed invention, Applicants point out that this rejection is moot in light of the amended claims.

To expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out the claimed subject matter. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Given that the amended claims are not directed to small molecule inhibitors of hedgehog signaling, this rejection based on the combination of the teachings of Fujita et al. and the teachings of US 6261786 is not applicable to the pending claims. Reconsideration and withdrawal of this rejection are respectfully requested.

6-7. Claims 1-15, 24-33 and 35 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that applicants had possession of the claimed invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

Applicants maintain the arguments of record and contend that the specification, in view of the level of skill in the art, provides ample support for the claimed subject matter. Applicants have further cited post-filing evidence which demonstrates that, as described by Applicants, one

of skill in the art can identify variant hedgehog polypeptides which function as antagonists of hedgehog signaling (Katsuura et al., 1999).

Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claims 1 and 2 to more explicitly point out certain embodiments of the present invention and have cancelled claims 3, 6-15 and 29-33. Cancellation of and amendments to the claims are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000.

If there are any other fees due in connection with the filing of this Reply, please charge the fees to our **Deposit Account No. 18-1945**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit account.

Respectfully Submitted,

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